

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	
<i>THIS DOCUMENT RELATES TO:</i>)	HON. PATTI B. SARIS
)	
COUNTY OF SUFFOLK,)	
)	Case No. 01-CV-12257 (PBS)
v.)	
)	
ABBOTT LABORATOIRES, INC., et al.)	
)	
E.D.N.Y case No. CV-03-229)	
)	

DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

On June 1, 2004, a justice of the Supreme Court of the State of New York, which is the trial court in New York, issued a decision in New York v. Pharmacia Corp., GlaxoSmithKline, PLC and Aventis Pharmaceuticals, Inc., Index Nos. 905-04, 905-03 and 1150-03 (Albany County) addressing a number of issues presently pending before this Court in connection with defendants' motion to dismiss the Suffolk County action, filed September 15, 2003. In an opinion dismissing three out of five causes of action for failure to plead the required elements, the court in that case dismissed the State's claim under N.Y. Social Services Law § 145-b for the same reasons articulated by defendants to this Court at oral argument on December 12, 2003. At the same time, the court denied the defendants' motion to dismiss the State's claim under N.Y. General Business Law § 349. The court did not address certain additional arguments raised by defendants in support of their motion to dismiss in this case. *See* Consolidated Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended

Complaint, filed Sept. 15, 2003, at 16 n.19, 20-22, 34-35; Consolidated Reply Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended Complaint, filed Nov. 14, 2003, at 7 n.8, 19.

A copy of the New York court's decision is attached.

Dated: June 14, 2004

Respectfully submitted

ON BEHALF OF ALL SERVED DEFENDANTS

By: /s/ Lucy Fowler
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CERTIFICATE OF SERVICE

I certify that on June 14, 2004, a true and correct copy of the foregoing Notice of Supplemental Authority was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.

/s/ Lucy Fowler
Lucy Fowler

EXHIBIT A

STATE OF NEW YORK
SUPREME COURT

ALBANY COUNTY

PEOPLE OF THE STATE OF
NEW YORK

Plaintiff,

Decision and Order
Index No. 905-04

-against-

PHARMACIA CORP.,

Defendant.

PEOPLE OF THE STATE OF
NEW YORK

Plaintiff,

Index No. 905-03

-against-

GLAXOSMITHKLINE, PLC, dba
GlaxoSmithKline; GLAXOWELLCOME, INC.,
d/b/a GlaxoSmithKline and SMITHKLINE
BEECHAM CORPORATION, d/b/a
GlaxoSmithKline,

Defendants.

PEOPLE OF THE STATE OF
NEW YORK

Plaintiff,

Index No. 1150-03

-against-

AVENTIS PHARMACEUTICALS,
INC.,

APPEARANCES:

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BENZA, J.:

By separate motions, defendants move this Court pursuant to CPLR 3211, to dismiss plaintiff's complaint in each of the above-referenced matters based on documentary evidence and for failure to state a cause of action.¹ The parties agreed to submit consolidated memorandum of law on the respective motions and, upon stipulation of the parties, set a schedule for briefing of the motions. These matters now being fully submitted, the Court makes the following determination.

In February 2003, plaintiff commenced three separate actions: State v Pharmacia

¹With respect to Index No. 905-03, plaintiff moved to withdraw its claims against defendants GlaxoSmithKline, P.L.C and Glaxo Wellcome, Inc, as the parties entered into an agreement for plaintiff to voluntarily dismiss any claims against these entities.

Corporation (Index No. 904-03), State v Glaxosmithkline, P.L.C., et al. (Index No. 905-03), State v Aventis Pharmaceuticals, Inc., (Index No. 1150-03). The allegations contained therein are relatively the same and are accepted as true for purposes of this motion (see, Skibinsky v State Farm Fire and Casualty Co., __ AD2d __, __, 775 NYS.2d 200, 201 [2004]).

Plaintiff alleges that government health plans, such as Medicare, Medicaid and Elderly Pharmaceutical Insurance Coverage program (hereinafter EPIC)² base reimbursement for covered drugs in large measure on the average wholesale price (hereinafter AWP) reported by defendants to price reporting agencies.³ Specifically, with respect to Medicare for physician-administered drugs, reimbursement is the lower of the amount the provider actually bills or 95% of the drug's AWP, with Medicare paying 80% of this cost and the consumer paying 20% as a co-payment (42 USC 1395 [u][o], 1395 [a]). Medicaid's cost reimbursement schedule for pharmacies is limited to the lower of the AWP, less 10 percent plus reasonable dispensing fees,⁴ or the customary charge for the drug of the provider to the public (42 CFR 447.331). On consumers covered under EPIC, there is no reimbursement for physician-administered drugs. The reimbursement to pharmacies is usually 90% of the AWP, or the pharmacy's usual charge to the public (Executive Law § 547-j [1] [b]).

Plaintiff alleges that defendants, all pharmaceutical manufactures, concealed the true AWP of their drugs from consumers, government agencies and drug price reporting services.

²EPIC is a voluntary program administered and funded by the State and covers drugs dispensed by pharmacies (Executive Law § 547-j [1],[b]).

³It is noted that AWP is not defined in any of the legislation relied on by the parties.

⁴ If the drug has an "upper limit", the amount can be no more than 150% of the published price for the least costly therapeutic equivalent (42 CFR 447.332).

After defendants report AWP's to price reporting agencies, these agencies report the AWP's to plaintiff. As a result, Medicare, Medicaid and EPIC rely on the reported AWP's to reimburse New York providers. Plaintiff alleges that defendants sell their drugs, through middlemen and directly, to doctors, healthcare providers and pharmacists at prices far less than the AWP, a practice referred to as "spread". As a result of defendants' misrepresentations of the AWP's and marketing the spread to physicians, pharmacists and other healthcare providers, plaintiff alleges that these providers are improperly induced to prescribe defendants' drugs, without consumer knowledge, and, as such, government payers and consumers pay artificially inflated sums.

The essence of plaintiff's complaint in each action is that the respective defendant (1) engaged in deceptive business practices in violation General Business Law § 349 (first cause of action), (2) perpetrated fraud in violation of Executive Law § 63 § (12) (second cause of action), engaged in commercial bribery in violation fo Penal Law § 180.00 (third cause of action), engaged in kickbacks in violation of 18 NYCRR 515.2 (b)(5) (fourth cause of action), and obtained funds through false statement in violation of Social Service Law § 145-b (fifth cause of action). Plaintiff seeks, inter alia, injunctive relief preventing further unlawful conduct, restitution to aggrieved consumers and the State, civil penalties and treble damages. The instant actions were removed to Federal Court, and then remanded back for this Court's consideration. Prior to joinder of issue, defendants in each of the separate actions moved to dismiss the respective complaint of plaintiff.

First Cause of Action - General Business Law § 349

In support of their respective motions and in their consolidated memorandum of law, defendants argue, inter alia, that plaintiff's complaint fails to state a claim because plaintiff was not deceived by the AWP as evidenced by government reports, regulatory and legislative history and public accounts, and plaintiff had the statutory right to request price information directly from defendant manufacturers. Further, defendants contend that plaintiff may not bring this action to recover losses to the State but may only recover restitution for consumers. Next, defendants argue plaintiff allegations are not sufficiently specific and, in any event, fail to establish a prima facie claim.

General Business Law § 349 declares as unlawful "[d]eceptive acts and practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state," with no further explanation of the conduct prohibited (Oswego Laborers' Local v Marine Midland, 85 NY2d 20, 26 [1995]; see, Stutman v Chemeical Bank, 95 NY2d 24, 29 [2000]). As a threshold matter, however, a plaintiff must allege conduct of the defendant that is consumer-oriented (see, Oswego Laborers' Local v Marine Midland, supra). Further, "a prima facie case requires * * * a showing that defendant is engaging in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof" (id.).

Here, the Court has no difficulty determining that plaintiff alleges conduct by defendants that is consumer-oriented as "the gravamen of the complaint [is] consumer injury or harm to the public interest" (Securitron Magnalock Corp. v Schnabolk, 65 F3d 256, 264 [1995] cert denied, 516 US 1114). Through intermediaries such as doctors and pharmacies, defendants' products are offered for sale for consumer consumption. Even if co-payments made by State-subsidized

consumers are not affected by defendants' alleged deception because most co-payments are a flat fee, and not based on a percentage of the drugs' cost, the public interest is harmed by overpayment from State coffers. Such action is, therefore, consumer-oriented (id).

Moreover, indeed, if plaintiff can establish its allegation that defendant artificially inflated prices reported to price reporting agencies known to be relied upon by governmental agencies for reimbursement purposes and the spread achieved thereto created increased profits to defendants through increased sales, such conduct would rise to the level of deception or misleading and, if established, this conduct would cause injury to plaintiff through increased reimbursements. In making this determination, the Court is mindful of the voluminous material submitted by defendants indicating that defendants' reporting of the AWP was neither deceptive nor misleading, nor the cause of any injury to plaintiff. At this juncture, however, the Court determines that plaintiff's allegations are adequately pled as required by CPLR 3013 and establish a prima facie claim, and that defendant's submissions do nothing more than raise potential factual issues which are not before the Court at this time.

Finally, the Court sees no difficulty with plaintiff seeking damages for harm to the State as a result of any alleged overpayment, as the purpose of the statute - consumer protection - is furthered. Moreover, the statute provides no limitation on the scope of relief afforded, and through the alleged overpayments by the State, the people of the State are harmed.

Accordingly, defendants' motions to dismiss plaintiff first cause of action is denied.

Second Cause of Action - Executive Law § 63 (12) - Fraud

Defendants contend that this cause of action must fail for the same reasons articulated in the previous claim, namely that inflation of AWP's was not deceptive or misleading because

government administrators were aware of defendants' practices, and plaintiff's lack of specificity in pleading its cause of action.

Executive Law § 63 (12) provides the Attorney General may bring an action "whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business". "The word 'fraud' or 'fraudulent' as used herein shall include any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions"(id). Such an action may seek: injunctive relief enjoining the continuance of such business activity or of any fraudulent or illegal acts, directing restitution and damages (id).

Initially, the Court notes that the elements of this claim are broader than the elements of a claim raised under General Business Law § 349 inasmuch as a claim under Executive Law § 63 (12) does not require consumer-oriented conduct (see, id.; see also, State v Feldman, 210 F.Supp2d 294, 300 [citing examples where statute used to seek relief for non-consumer protection actions]). As such, the Court does not deem this claim to be duplicitous of plaintiff's first cause of action inasmuch as the elements of the claim are not the same. Moreover, the Court determines that plaintiff has adequately alleged a prima facie claim for this cause of action inasmuch as plaintiff's allegations, if proven, establish a repeated misrepresentation by defendants in conducting its business and, thus, state a claim for relief. Accordingly, defendants' motions to dismiss plaintiff's second cause of action is denied.

Third Cause of Action - Commercial Bribery/Penal Law § 180

Defendants contend, inter alia, that plaintiff has failed to adequately plead this claim and failed to allege that defendants conferred any benefit to any provider in violation of the statute. The Court agrees.

Penal Law § 180 provides that "a person is guilty of commercial bribing * * * when he confers, or offers or agrees to confer, any benefit upon any employee, agent or fiduciary without the consent of the latter's employer or principal, with intent to influence his conduct in relation to his employer's or principal's affairs". As such, to adequately plead a claim for commercial bribery, a plaintiff must allege "that defendants conferred a benefit upon plaintiff's employee, [agent or fiduciary] without plaintiff's consent and with the intent to influence the employee's [principal's] conduct" (Niagara Mohawk Power Corp. v Freed, 265 AD2d 938, 939 [1999]). Here, plaintiff's allegations do not establish these elements. Plaintiff argues that it has satisfied the statutory criteria because it alleges that physicians have a fiduciary relationship with their patients, and defendants have offered these providers a benefit on defendants' respective drugs without the consent of the physicians' patients/principals. The Court determines that the act of defendants notifying pharmacists or physicians about the spread, is not conferring a benefit within the meaning of the statute. Rather, the benefit that plaintiff alleges is not from defendants, but from the regulatory mechanism that provides the reimbursement. Accordingly, inasmuch as plaintiff's allegations do not establish a prima facie claim, plaintiff's third cause of action in the respective complaints is dismissed.

Fourth Cause of Action - Kickbacks/ 18 NYCRR 515.2 (b)(5)

Defendants contend, inter alia, that plaintiff fails to plead this claim with sufficient

specificity because it fails to allege a single kickback for a particular drug sold. Plaintiff argues that defendants fraudulently created a spread and marketed this spread to providers as a quid pro quo to induce the providers to recommend defendants' drugs in violation of 18 NYCRR 515.2 (b)(5)(iv).

The pertinent regulation, 18 NYCRR 515.2 (b)(5) provides:

Unless the discount or reduction in price is disclosed to the client and the department and reflected in a claim, or a payment is made pursuant to a valid employer-employee relationship, the following activities are unacceptable practices:

(iv) **offering or paying** either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program.

The Court determines that plaintiff's allegations do not adequately allege that defendants offered any kickback or bribe, or paid any kickback or bribe, to providers in return for using defendants' drugs. At most, as stated previously, defendants made providers aware of the spread and the government program made the payment. There is no allegation that providers received the spread in exchange for recommending the drug or that the spread changed with the volume of the drug used. As such, the Court determines that this is not a direct or indirect offer or payment within the meaning of the regulation. Further, the Court notes that plaintiff has failed to allege any facts that establish a provider recommended a drug to a client or patient as a result of defendants' actions or that defendants' offered the only drugs for a particular condition. Accordingly, plaintiff has not alleged a prima facie claim on this cause of action and defendants' motion to dismiss the fourth cause of action is granted.

Fifth Cause of Action - Social Service Law § 145-b

Defendant again contends that plaintiff's allegations are deficient due to lack of factual specificity and, further, that defendants have not violated the statute because they do not receive public funds. Plaintiff counters that the statute does not restrict violations to only those individuals receiving actual payments from State funds.

Social Service Law § 145-b provides, in pertinent part,

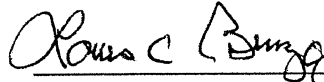
It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

Here, there is no allegation that defendants received any public funds as a result of their actions, as required by the plain language of the statute (see, e.g., People v Brooklyn Psych. Rehab. Institute, 185 AD2d 230, 234 [1992], lv denied 81 NY2d 702). As such, plaintiff has failed to establish the requisite elements of its claim and, therefore, fails to state a claim. Accordingly, defendants' motion to dismiss plaintiff's fifth cause of action is granted.

Based on the foregoing, the motions to dismiss of defendants Pharmacia Corp., SmithklineBeecham Corporation, d/b/a GlaxoSmithKline, and Aventis Pharmaceuticals, Inc. are granted to the extent that plaintiff's third, fourth and fifth causes of action are dismissed; all other relief is denied. This memorandum constitutes the Decision and Order of this Court. All papers including this Decision and Order are returned to attorney for defendant Pharmacia Corp - John M. Vasso, Esq. The signing of this Decision and Order shall not constitute entry or filing under CPLR 2220. Counsel is not relieved from the applicable provisions of this rule with

regard to filing, entry and Notice of Entry.

Albany, New York
June 1, 2004



Hon. Louis C. Benza, JSC

Papers Considered

1. Notice of Motion dated December 1, 2003 - Index No. 904-03
2. Notice of Motion dated December 1, 2003 - Index No. 905-03
3. Notice of Motion dated December 1, 2003 - Index No. 1150-03
4. Consolidated Affirmation of Neil L. Levine dated December 1, 2003; exhibits A-Z annexed;
5. Affirmation of Rose Firestein dated January 31, 2004; exhibits 1-19
5. Stipulation and Order dated November 18, 2003
6. Stipulation and Order dated February 11, 2004~~1~~